

Steven C. Anderson, CAE

President and
Chief Executive Officer

September 2 1, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. **99N-0438**

Dear Sir or Madam:

The National Restaurant Association appreciates the opportunity to submit its views on the Food and Drug Administration's (FDA) public meeting regarding "Bare-Hand Contact of Ready-To-Eat Foods" Federal Register: August 13, 1999, Vol 64, No. 156, pages 44225 to 44226. As leaders of the hospitality industry, we have a long-standing commitment to food safety and the protection of our customers---and are deeply interested in improving and responsibly addressing retail food safety.

Founded in 1919, the National Restaurant Association is the leading business authority for the nation's \$336 billion restaurant industry, which has more than 810,000 restaurant locations. Our 37,000 members represent more than 170,000 individual **fullservice** restaurants, quickservice units and cafeterias, institutions, hospitals, universities, and military clubs. We have made multi-billion dollar investments in improving restaurant food safety and developing state-of-the-art food-safety education programs during the past 80 years. In cooperation with state and local health officials, the National Restaurant Association has been a partner in the development of numerous state food-safety regulations, food-safety educational programs and informational materials based upon industry research, current science and **Hazard** Analysis Critical Control Point. We have also worked for more than 20 years to improve hand-washing compliance at retail through our food-safety education-and-training programs, such as **ServSafe**.

We would like to commend the FDA for its efforts to solicit comments **from** the industry and the public on the issue of bare-hand contact. The current FDA regulatory scheme to absolutely ban bare-hand contact as noted in the 1999 FDA Food Code is impossible to comply with and not supported by scientific data [Fendler et al., Part I, 1998]. We believe that food contact with unwashed, contaminated hands or gloves can be a source of foodborne illness [Torok et al., 1997], and that responsible and effective action should be taken to address this problem.

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However, rather than the unrealistic prohibition of all bare-hand contact, we believe the solution lies in improved hand-washing compliance and effective hand-washing management at retail [Sattar and Springthorpe, Cambridge University Press, 1996]. Furthermore, all bare-hand-to-food contact does not involve the same level of risks as those which involve greater intimacy, regularity or volume of exposure. The key to improved food safety is a proper hand-washing focus and the elimination of dirty, bare-hand contact where appropriate. Simple “silver-bullet” solutions like mandatory glove use or banning bare-hand contact may be attractive, but practical information must be fully considered before any effective solution can be developed and implemented [Fendler et al., Part II, 1998; Docket RPT-1].

The absolute prohibition of bare-hand contacts or mandatory glove rule surfaced in the 1993 FDA Food Code and has been addressed in numerous regulatory meetings, and state and local government hearings since that time. As a result of the increased attention, many in the restaurant industry, and state and local regulatory officials have implemented effective hand-washing intervention and regulatory strategies Florida alternative, 1998, and California, CURFFL, 1999]. The 1999 FDA Food Code recognized effective hand-washing management in Annex 3. However, the code language-which absolutely prohibits bare-hand contact--did not change to reflect the current public-health reasoning regarding hand-washing compliance and management.

Since 1993—and particularly after the 1997 version of the FDA Food Code-states began adopting the FDA Food Code and provisions, many with realistic changes to the bare-hand-contact prohibition in section 3-301.11. Texas, California and Florida-the three most notable examples-have been able to effectively work with the industry to improve hand-washing compliance, protect public health and allow limited bare-hand contact at retail. Clearly these states, by their actions, have determined that there is no conclusive evidence that the mandatory use of gloves or utensils affords any greater level of protection in a restaurant setting than clean washed hands. Furthermore, their solutions recognized that, in foodservice settings, there are many circumstances in which it is logistically impossible to avoid all bare-hand contact with ready-to-eat foods. Common kitchen tasks such as peeling shrimp, filling tacos, peeling fruit and working with hot equipment all potentially require direct hand contact.

In addition, we have seen no evidence that glove use has reduced the transmission of foodborne illness or lowered the number of foodborne illnesses in the few states that have implemented mandatory-glove laws [CDC, **FoodNet 1998**]. From 1995 through 1998, epidemiological data developed through the Center for Disease Control's (CDC) **FoodNet** data has also shown a significant lowering of foodborne illnesses per 100,000 population nationwide. The reductions in illnesses since 1995 may reflect the effective implementation of strategies incorporated at various steps by the food industry, including hand-washing management. In previous data [CDC summary, 1989 to **1992**], the CDC cited poor personal hygiene as a cause of illness less than 25 percent---one **in four/five**---of the time when the cause was identified. Improper holding temperatures were cited 35 percent of the time as the number-one cause in all years. Since the CDC term "personal hygiene" may encompass many practices, of which hand contact is only one, the real percentage because of dirty-hand contact is likely to be significantly smaller. In any case, the absolute number of illnesses associated with dirty-hand contact is probably declining and does not represent a growing or out-of-control problem.

We continue to believe that the ultimate solution to reducing poor-personal-hygiene and dirty-hand-contact associated illnesses is an **effective** education-and-training program highlighting hand-washing and hand-washing management. The National Restaurant Association Educational Foundation developed and offers this training today through its **ServSafe** program. We challenge others to join us in increasing the 1 million restaurant managers already trained and certified in **our** food-safety education program. Through consistent training, we can improve hand-washing compliance and management.

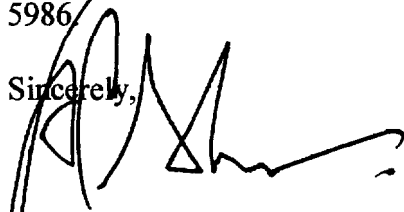
The National Restaurant Association is not opposed to appropriate glove use and the reduction of bare-hand contact. We have consistently supported a balanced approach that calls for effective hand washing and the use of gloves for high-risk situations. This philosophy recognizes that there are no silver-bullet solutions and that no one strategy is totally appropriate for all restaurant situations [**Fendler et al., Part II, 1998**].

The FDA and others have noted some failings of the current levels of hand-washing compliance and management on many occasions and we agree-more work does need to be done to improve hand-washing compliance and management. However, the issue must be addressed directly. We welcome the opportunity to cooperatively develop **hand-**washing compliance education-and-training programs. But we should not expect any real improvement in hand-washing compliance if we continue to cover the real problem with gloves [Bardell, 1995] or attempt to eliminate bare-hand contact. Research has clearly shown that glove use is not an absolute barrier and may even add more problems parson et al., 1989; Ehrenkranz, 1992; DeGroot-Kosolcharoen, et al., 1989; and Fendler et al., Part I, 1998]; sole reliance on glove use may only complicate the existing compliance issues.

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The National Restaurant Association welcomes increased cooperative efforts to address the problem of food contamination and personal hygiene. We consistently strive to develop and improve the effectiveness of employee-training materials, and we appreciate the opportunity to comment on this issue. If you have any questions or comments, please call Steven Grover, Vice President of Health and Safety Regulatory Affairs, at (202) 331-5986.

Sincerely,

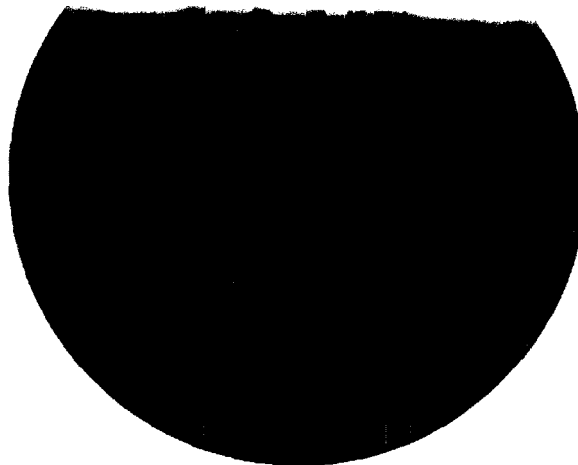
A handwritten signature in black ink, appearing to read 'S. Anderson', written over the word 'Sincerely,'.

Steven C. Anderson
President and Chief Executive Officer

cc: Peter Kilgore, Senior Vice President and General Counsel
Steven Grover, Vice President of Health and Safety Regulatory Affairs

References

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